

Notice of Allowability

Application No.

10/822,260

Examiner

Karen E. Toth

Applicant(s)

COYLE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 22 February 2007.
2. ☒ The allowed claim(s) is/are 47-52, 54, 55, 57-70, 78 and 79.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

DETAILED ACTION

Allowable Subject Matter

1. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to anticipate or make obvious the method of claims 47 and 48, including, *inter-alia*, identifying cough or sigh events from lung volume signals by deriving temporal sequences of respiratory parameters and identifying artifacts (coughs or sighs) when the sequence does not meet the "true breath rule" – that is, a breath is considered a "true breath" if the difference between the previous breath's end expiratory volume and the current breath's end expiratory volume is less than a fixed ratio times V_{t-cal} , where the ratio is preferably between 200% and 300%.

The prior art of record fails to anticipate or make obvious the method of claim 49, including, *inter-alia*, deriving temporal sequences of respiratory parameters from lung volume signals and recognizing periods of speech by a subject as dependent upon inspiratory/expiratory ratio, fractional inspiratory time, inspiratory flow rate, and/or expiratory time.

The prior art of record fails to anticipate or make obvious the method of claim 50, including, *inter-alia*, deriving temporal sequences of respiratory parameters from lung volume signals and recognizing dyspnea, or shortness of breath, as dependent upon the ratio of minute ventilation volume to peak expiratory flow.

The prior art of record fails to anticipate or make obvious the method of claim 51 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the

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ratio as being dependent upon the ratio of time to reach peak expiratory flow to expiratory time or the ratio of peak expiratory flow and mean expiratory flow.

The prior art of record fails to anticipate or make obvious the method of claim 52 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the ratio of peak inspiratory flow to tidal volume.

The prior art of record fails to anticipate or make obvious the method of claim 54 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the rib cage's contribution to the tidal volume.

The prior art of record fails to anticipate or make obvious the method of claims 55, 78, and 79 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon a temporal sequence of the fraction of expiration time with thoraco-abdominal asynchrony as derived from signals reflective of rib cage size and abdominal size.

The closest prior art to the above claims includes Ni (US Patent Application 2004/0111040), Sackner (US Patent 6015388), Kihara (US Patent Application Publication 2004/0143194), and Anderson (US Patent 4463764).

Ni discloses a method for recognizing respiratory events comprising deriving a signal indicative of lung volume from a plurality of respiratory signals from a monitored subject (paragraphs [0045], [0051]-[0052], [0058]); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (paragraphs [0053]-[0055]); and recognizing one or more respiratory events in

dependence on at least one of the derived temporal sequences of respiratory parameters (paragraphs [0055]-[0056], [0059]).

Sackner discloses a method for recognizing respiratory events comprising deriving a signal indicative of lung volume from a plurality of respiratory signals from a monitored subject (column 14, lines 50-53); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (column 14, lines 38-41; column 16, lines 32-38); and recognizing one or more respiratory events in dependence on at least one of the derived temporal sequences of respiratory parameters (respiratory drive may be considered a respiratory event; column 16, lines 32-38).

Kihara discloses a method of monitoring respiration comprising deriving a signal indicative of lung volume from a plurality of respiratory signals gathered from a monitored subject (paragraphs [0008]-[0009], [0020]); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (paragraphs [0020]-[0021], [0122], [0125]-[0126]); and recognizing one or more respiratory events dependent on at least one of the derived temporal sequences of respiratory parameters (paragraphs [0125]-[0126]).

Anderson discloses a method of monitoring respiration comprising deriving a signal indicative of lung volume from a plurality of respiratory signals gathered from a monitored subject (column 2, lines 5-28; column 5, lines 9-15); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (column 6, lines 14-17); and recognizing one or more respiratory events dependent on

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at least one of the derived temporal sequences of respiratory parameters (column 15, lines 46-50).

2. The prior art of record fails to anticipate or make obvious the method of claims 57-70, including, *inter-alia*, determining the occurrence of a cough when both sound event signals and lung volume signals showing cough event characteristics temporally coincide.

Gavriely (US Patent 6261238) discloses recognizing a candidate cough sound event when a sound signal from a microphone recording vocalizations exceeds a threshold, comparing the sound signal to a respiration monitor to ensure that the sound coincides with a respiration event, and determining that a cough has occurred based on the sound signals. Gavriely does not disclose additionally filtering a lung volume signal in response to characteristics of the sound event, recognizing a candidate event based on tidal volume signals exceeding a threshold, and determining the cough's occurrence only when the lung volume and sound signals coincide.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

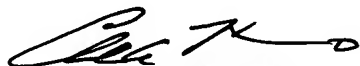
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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